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Remarks

Applicants have hereby cancelled Claims 1, 4, and 34-35; amended Claims 31 and 32; and added Claims 40-53. Claims 2-3, 5-19, 21-30, and 39 stand withdrawn, and may be pursued in a continuing application. All independent claims, and claims that depend therefrom, require pudendal nerve stimulation within the presently elected species ("the perineal approach"). The claims, as amended and as newly added, should be in condition for allowance.

Claim Rejections - 35 USC § 102

The Examiner rejected Claims 1, 4, and 31-35 under 35 U.S.C. 102(b) as being anticipated by Lue, et al. (Pat. No. 4,585,005; "the '005 patent"). Claims 1, 4, and 34-35 have been cancelled. Claims 31-32, have been amended as mentioned above. Claim 33 depends from amended independent Claim 31.

In order for a reference to anticipate a claim under 35 U.S.C. 102(b), the reference must teach every element of the claim. Lue, et al. do not teach stimulation of the pudendal nerve as claimed. See MPEP 2131. Although the Examiner "considers the nerves shown in Fig. 1 to originate from the sacral nerve roots and incorporate a pudendal nerve" (Office action, page 2); Lue, et al. teach the contrary: "electrode 11 is implanted on each of a pair of the patient's cavernous nerves" (see Col. 5, lines 52-53 and Col. 4 generally) rather than the pudendal nerve or any of the other various nerves that originate from the sacral nerve roots. The word "pudendal" appears nowhere in the '005 patent. Lue, et al. do not indicate that the pudendal nerve is shown in FIG. 1. Even if the pudendal nerve were shown in FIG. 1; Lue, et al. limit their teachings throughout the '005 patent to stimulation of the cavernous nerve to produce

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erection in a male patient. Because Lue, et al. do not teach stimulation of the pudendal nerve as required by all amended and newly added independent claims, the '005 patent does not anticipate the claims.

In addition, the perineal approach steps required by dependent Claim 41, upon which Claims 42-49 depend, is not taught by the '005 patent. The '005 patent merely teaches a method of implanting an electrode on the cavernous nerves, rather than the pudendal nerve via a perineal approach, as described, for example, on pages 26-27 of the present application. Thus, in addition to the reasons above, Claims 41-49 are in condition for allowance because the steps of Claim 41 are not taught by Lue, et al.

Further, the Examiner rejected Claim 1 under 35 U.S.C. 102(b) as being anticipated by Tahagho, et al. (Pat. No. 4,607,639; "the '639 patent"). Claim 1 has been cancelled. The '639 patent also fails to anticipate all other independent claims because Tanagho, et al. do not teach pudendal nerve stimulation as claimed. Tanagho, et al. teach *sectioning* the pudendal nerve in order to isolate it from the stimulation of a separate nerve of the sacral nerve roots. Specifically, Tanagho, et al. state, "[p]udendal or inferior somatic nerve S, is then sectioned unilaterally to isolate external sphincter E on one side." Col. 6, lines 59-60; see also section S, of FIG. 3. Sectioning, (a different procedure than implanting an electrode (see Col. 5, lines 3-4) as required by the claims), is a procedure of cutting or severing the nerve of a patient. For additional examples of nerve sectioning as taught by Tanagho, et al., see FIG. 1, reference numeral 3; FIG. 3, reference numerals 2a, 4a, and 5a; and FIG. 4, reference numeral 3'. Because Tanagho, et al. specifically teach sectioning the pudendal nerve rather than stimulating the pudendal nerve (by, e.g., implanting an electrode adjacent to the pudendal nerve), and

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because all claims require pudendal nerve stimulation, the '639 patent does not anticipate the claims as amended and as newly presented.

Claim Rejections - 35 USC § 103

The Examiner rejected Claims 36-38 under 35 U.S.C. 103(a) as being unpatentable over Lue, et al. in view of Whitehurst, et al. (Pat. No. 6,650,943; "the '943 patent"); Claims 4 and 31-35 over Tanagho, et al. in view of Lue, et al.; and Claim 36 over Tanagho, et al. in view of Lue et al. and further in view of Roe et al. (Pat. No. 6,266,557; "the '557 patent"). Claims 4 and 34-35 have been cancelled. Claim 31, and all claims that depend therefrom, has been amended to require pudendal nerve stimulation.

A prima facie case of obviousness requires at least that "the prior art reference (or references when combined) must teach or suggest all the claim limitations". MPEP 2143. The references cited by the Examiner above fail to teach or suggest all the limitations of the claims as amended and newly added. All currently-pending independent claims require pudendal nerve stimulation. As established above, neither the '005 patent nor the '639 patent teach or suggest the use of pudendal nerve stimulation. Rather, both references teach away from such stimulation (as the '005 patent focuses solely on cavernous nerve stimulation to cause erection in a male patient and the '639 patent teaches sectioning the pudendal nerve, not stimulating it). Further, neither the '943 patent nor the '557 patent cited by the Examiner teach or suggest pudendal nerve stimulation as claimed. Specifically, the '943 patent teaches cavernous nerve stimulation for erectile or other sexual dysfunction rather than pudendal nerve stimulation. And, the '557 patent teaches detecting electrical activity of the sphincter muscle rather than pudendal nerve stimulation as claimed. Because the references cited in combination by the Examiner do

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not collectively teach or suggest pudendal nerve stimulation as claimed, the claims as amended and as newly added, should be in condition for allowance.

Conclusion

In view of the foregoing, it is respectfully submitted that the independent claims as amended and as newly added, and all claims that depend therefrom, are in condition for allowance. An indication of allowability of Claims 31-33, 36-38, and 40-53 is earnestly solicited.

The Examiner is invited to telephone the undersigned, Bryant R. Gold, at his convenience should any issues remain after consideration and entry of this response, in order to permit early resolution of the same.

Respectfully Submitted,

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